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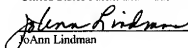
Application No.: 10/621,972
Applicant: Ross S. Tsugita
Filed : July 17, 2003
Title: FILTER FLUSH SYSTEM AND METHODS OF USE
Docket No.: 1001.1421103

Confirmation No.: 2230
TC/A.U. : 3731
Examiner : Thaler, Michael H.
Customer No.: 28075

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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 10-24-07
JoAnn Lindman Date

Applicants have carefully reviewed the Final Office Action dated May 8, 2007 and the Advisory Action dated August 14, 2007. Currently, claims 32-52 are pending in the application, claims 47-52 have been withdrawn from consideration, and claims 32-46 have been rejected. Applicants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. It is noted that the amendment filed July 30, 2007 was not entered by the Examiner for the purposes of this appeal. Favorable consideration of the claims is respectfully requested. Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

On page 2 of the Final Office Action, claims 32-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gray (WO 99/22673) in view of Littleford et al. (U.S. Patent No. 5,054,500). Applicant must respectfully traverse this rejection.

Claim 32 recites:

32. A medical device for use in a body lumen, the device comprising:
a first catheter shaft having a proximal end region, a distal end region, and
a guidewire lumen;
a guidewire slidably disposed in the guidewire lumen;
a filter coupled to the guidewire;
a balloon coupled to the distal end region of the first catheter shaft; and
a stent disposed adjacent the first catheter-shaft and positioned distally of
the balloon,

wherein the balloon and the first catheter shaft are configured to stop fluid from outside the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). (See MPEP § 2143.03). Nowhere does the combination of Gray and Littlefield et al. appear to teach or suggest, “wherein the balloon and the first catheter shaft are configured to stop fluid from outside the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded”, as recited in claim 32.

Instead, the balloon of Littlefield et al. appears to allow fluid to flow outside the first catheter shaft from a position proximal the balloon to a position distally past the distal region of the shaft when the balloon is expanded. See for example, Figure 9 of Littlefield et al., which illustrated fluid channels 58 to prevent the expanded membrane 24 from completely blocking the blood vessel and restricting blood flow. (See also column 5, lines 7-15). Therefore, for at least this reason, Gray and Littlefield et al. appear to fail to teach all the claim limitations. Thus, claim 32 is believed to be patentable over Gray in view of Littlefield et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 34, which recites:

34. The medical device of claim 32, further comprising a second catheter shaft slidably disposed within the first catheter shaft.

Claim 34 recites, in part, a second catheter shaft slidably disposed within the first catheter shaft. Nowhere does the combination of Gray and Littleford et al. appear to teach or suggest such a limitation.

In the Final Office Action, the Examiner acknowledges that Gray fails to disclose a first catheter shaft and relies upon Littleford et al. as teaching a the first catheter, indicated as guiding catheter 20. However, nowhere does Littlefield et al. appear to teach a second catheter shaft slidably disposed within the first catheter shaft, as recited in claim 34. For at least this reason, the combination of Gray and Littlefield et al. fails to establish a *prima facie* case of obviousness because the combination fails to teach all the claim limitations. Therefore, claim 34 is believed to be patentable over Gray in view of Littlefield et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons and others, claims which depend from claim 32 and/or 34, are believed to be patentable over Gray in view of Littlefield et al.

Turning to claim 41, which recites:

41. (Previously Presented) A medical device for use in a body lumen, the device comprising:
an outer catheter shaft;
an inner catheter shaft slidably disposed in the outer catheter shaft;
an elongate guidewire slidably disposed in the inner catheter shaft;
a filter coupled to the guidewire;
a balloon coupled to the outer catheter shaft; and
a stent coupled to the inner catheter shaft,
wherein the balloon and the outer catheter shaft are configured to stop fluid from outside the outer catheter shaft proximal to the balloon blood from flowing distally past the balloon when the balloon is expanded.

As can be clearly seen, claim 41 recites “an outer catheter shaft”, “an inner catheter shaft slidably disposed in the outer catheter shaft”, and “wherein the balloon and the outer catheter shaft are configured to stop fluid from outside the outer catheter shaft proximal to the balloon blood from flowing distally past the balloon when the balloon is expanded”. As discussed above, the combination of Gray and Littlefield et al. appears to fail to teach both an outer catheter shaft and an inner catheter shaft. Therefore, for similar reasons discussed above, as well as others, claim 41 is believed to be patentable over Gray in view of Littlefield et al. and Applicant respectfully requests withdrawal of the rejection.

For similar reasons and others, claims 42-46, which depend from claim 41 and include significant additional limitations, are believed to be patentable over Gray in view of Littlefield et al.

On page 3 of the Final Office Action, claims 32-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Garza et al. (U.S. Patent No. 4,665,918) in view of Hawkins et al. (U.S. Patent No. 4,790,812) and Littleford et al. Applicant must respectfully traverse this rejection.

As discussed previously, claim 32 recites, in part, “wherein the balloon and the first catheter shaft are configured to stop fluid from outside the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded”.

Littlefield et al. is the only one of the cited references that appears to teach a balloon, but, as discussed previously, Littlefield et al. appears to fail to teach the balloon and the first catheter shaft are configured to stop fluid from outside the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded. Thus, the combination of Garza et al., Hawkins et al, and Littlefield et al. appear to fail to teach all the claim limitations.

In rejecting claims under 35 U.S.C. § 103, the Examiner bears the burden of establishing a prima facie case of obviousness. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) (citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). Furthermore, where the Examiner relies on a combination of disclosures, the Examiner must provide sufficient evidence to show that one having ordinary skill in the art would have done what Applicant did. *United States v. Adams*, 383 U.S. 39 (1966); *In re Kahn*, 441 F.3d 977, 987-988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick, Co.*, 464 F.3d 1356, 1360-1361, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). The mere fact that all the claimed elements or steps appear in the prior art is not per se sufficient to establish that it would have been obvious to combine those elements. *United States v. Adams*, *Id.*; *Smith Industries Medical Systems, Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1420 (Fed. Cir. 1999). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Applicant respectfully asserts that there is no motivation in the references to make the claimed combination, without the use of impermissible hindsight. Therefore, for at least these reasons, claim 32 is believed to be patentable over Garza et al. in view of Hawkins et al. and Littlefield et al. For similar reasons, claims 33-40, which depend from claim 32, are believed to be patentable over Garza et al. in view of Hawkins et al. and Littlefield et al.

Referring to claim 41, which recites, in part, “an outer catheter shaft”, “an inner catheter shaft slidably disposed in the outer catheter shaft”, and “wherein the balloon and the outer catheter shaft are configured to stop fluid from outside the outer catheter shaft proximal to the balloon blood from flowing distally past the balloon when the balloon is expanded”. As discussed above, the combination of Garza et al., Hawkins et al., and Littlefield et al. appears to fail to teach all the limitations and fail to provide motivation to combine the references. Therefore, for similar reasons discussed above, as well as others, claim 41 is believed to be patentable over Garza et al. in view of Hawkins et al. and Littlefield et al. and Applicant respectfully requests withdrawal of the rejection.

For similar reasons and others, claims 42-46, which depend from claim 41 and include significant additional limitations, are believed to be patentable over Garza et al. in view of Hawkins et al. and Littlefield et al.

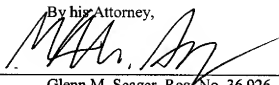
In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,

Date: Oct. 24, 2007


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